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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/683,399 | 12/21/2001 | Brian J. Martinell | 38-21(51470) | 2956 |

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MONSANTO COMPANY
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EXAMINER

HELMER, GEORGIA L

ART UNIT PAPER NUMBER

1638

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 09/683,399 | Applicant(s) MARTINELL ET AL. | |
| | Examiner Georgia Helmer | Art Unit 1638 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Status of the Claims

1. The Office acknowledges receipt of Applicant's Amendment after Final dated 13 February 2006.
2. The Finality of the previous Office Action is withdrawn.
3. Claims 1-19 are pending, and are examined in the instant action.
4. All rejections not addressed below have been withdrawn.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

6. Claims 1-11, 13-14 and 16-19 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6, 384,301 (hereafter '301).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e).

This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Applicant claims a method of early identification of germline transformed plants comprising steps of: (a) transforming meristematic or cotyledonary tissue with a plant expressible construct comprising at least one nucleic acid sequence encoding a protein to obtain transformed plant tissue; (b) producing a shoot from the transformed plant tissue; (c) growing roots from the shoot; (d) obtaining a piece of root tissue or extract thereof from the transformed plant tissue; assaying the root tissue or extract thereof for the presence of the nucleic acid sequence and (e) identifying roots that assay positive for said at least one nucleic acid sequence as putative germline transgenic plants.

Dependent claims are drawn the method wherein the plant expressible construct encodes a protein conferring a trait to the plant, the plant expressible construct comprises at least two nucleic acid sequences, wherein the roots are grown in the present of a selection agent; wherein the selection agent is kanamycin; wherein the selection agent is glyphosate; wherein the transformation is via *Agrobacterium* mediated transformation or particle mediated transformation; wherein the plant is a dicot plant; a soybean plant, or a cotton plant.

Further claims are drawn to a method of obtaining of germline transformed plant cells via kanamycin selection comprising steps of: (a) providing a heterologous DNA comprising a promoter function al. in plants transforming meristematic or cotyledonary tissue with a plant expressible construct comprising at least one nucleic acid sequence encoding a protein to obtain transformed plant tissue; (b) inserting a DNA construct into the meristematic tissue of a plant embryo; producing a shoot from the transformed plant tissue; (c) inducing shoot formation from the treated meristematic tissue by culturing on

a culture medium; (d) culturing the shoots on a suitable shooting media containing kanamycin at a concentration sufficient to significantly inhibition the growth of untransformed plant cells to generate kanamycin resistant shoots; (e) regenerate the shoot of step (d) into genetically transformed plants having increased tolerance to kanamycin relative to wild-type plants; assaying the roots form the plants of step (e) for the presence of the DNA construct; and identifying roots that assay positive for the DNA construct as putative germline transformed plants.

US 6,384,301 teaches a method of identification of germline transformed soybean (claims 13 and 14) cells and plants comprising steps of: (a) transforming meristematic tissue (column 7, lines 24-25) with a plant expressible construct comprising at least one nucleic acid sequence encoding a protein (column 7, lines 30) to obtain transformed plant tissue; (b) producing a shoot (column 7, lines 43-49) from the transformed plant tissue; (c) growing roots from the shoot (column 7, lines 43-49);

(d) obtaining a piece of root tissue or extract thereof from the transformed plant tissue, assaying the root tissue or extract thereof for the presence of the nucleic acid (column 4, lines 60-63 and column 9, lines 32-43) and (e) identifying roots that assay positive for said at least one nucleic acid sequence as putative germline transgenic plants (column 4, lines 60-63 and column 9, lines 32-43). Dependent claims are drawn the method wherein the plant expressible construct encodes a protein conferring a trait to the plant, the plant expressible construct comprises at least two nucleic acid sequence, wherein the roots are grown in the present of a selection agent; wherein the

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selection agent is kanamycin; wherein the selection agent is glyphosate; wherein the transformation is via *Agrobacterium* mediated transformation or particle mediated transformation; wherein the plant is a dicot plant; a soybean plant, or a cotton plant.

Soybean is a dicot plant (claim 13 and 14). Glyphosate is an herbicide (claim 2).

Claim 1 (d) has been amended to recite "obtaining a piece of root tissue or extract thereof from the transformed plant tissue, assaying the root tissue or extract thereof for the presence of the nucleic acid sequence".

The term "piece" is interpreted broadly to include pieces of indeterminate or variable size, from very large to very small, of root tissue. Accordingly, the language of the '301 reference, column 9, lines 32-43, which says:

"Of the seven target of 12 embryos for the treatment group, three phenotypic shoots were observed, one of these rooted and was sent to the greenhouse. It tested positive for GUS tissue in the vascular tissue, which indicates germline transformation..." is interpreted to say that a piece of the root was rooted and tested positive for GUS. The GUS assay is used to demonstrate the expression of the *uidA* reporter gene.

Furthermore, the '301 patent, column 4, lines 60-63, says "the elongated shoots...are placed on a rooting medium to induce root formation." And "[r]oot formation takes approximately 1-4 weeks, following which the plants can be transferred to soil and grown to full maturity. Ideally, the rooting medium also contains the selection agent...."

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The language "assaying for the presence of the nucleic acid sequence" is interpreted to encompass growing the roots in the presence of the selective agent, kanamycin or glyphosate.

The transformation method used is Agrobacterium mediated transformation (column 5, lines 18-41) (claim 8).

Accordingly, '301 anticipates the claimed invention

Claim Rejections - 35 USC § 103

7. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,384,301 as applied to claims 1-11, 13-14 and 16-19 above, in view of US 5,994,624.

US 6,384,301 does not teach the use of PCR, RT -PCR or Southern blot to assay the roots from the shoots (claim 12) and does not teach transformation of cotton (claim 15).

However, US 6,384,301 does teach the use of PCR of leaf tissue of transgenic plants (column 8, lines 59-60) for confirmation of the germline transformation of the tissue.

US 5,994,624 teaches the germline transformation of cotton (Example I, column 10, line 15-column 12, line 3). The US 5,994,624 patent also teaches the use of soybean in place of cotton (column 13-14, claims 5-10) in the germline transformation process.

It would have been obvious to one of skill in the art, at the time of the invention was made, to use the PCR assay of the '301 patent to assay root tissue as well as leaf

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tissue, as PCR assays have been shown to function well in the confirmation of the presence of specific nucleic acid sequences in transgenic plant tissue in general.

Furthermore, it would have been obvious to one of skill in the art, at the time of the invention was made, to substitute for the soybean of '301, the cotton of US 5,994,624, since the US 5,994,624 patent teaches the use of soybean as well as cotton (column 13-14, claims 5-10) in the germline transformation process. One skilled in the art would have been motivated to so, with a reasonable expectation of success, especially in the absence of evidence to the contrary, given the suggestion by US 5,994,624 and the success of US 6,384,301.

Accordingly, the claimed invention is prima facie obvious in view of the prior art.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-9 and 13-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 and 13 of U.S. Patent No. 6,384,301. Although the conflicting claims are not identical, they are not patentably distinct from each other because the species claims of patent 6,384,301 renders the genus claims of the instant application obvious.

This is a provisional obviousness-type double patenting rejection since no claims have been allowed in the instant case.

Remarks

10. Claims 1-19 are not allowed in view of the prior art.

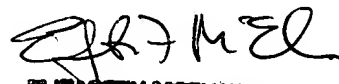
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia Helmer whose telephone number is 571-272-0796. The examiner can normally be reached on 10-6 Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia Helmer PhD
Patent Examiner
Art Group 1638
April 27, 2006


ELIZABETH HELMER
PRIMARY EXAMINER